



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive License:** Her2 Monoclonal Antibodies, Antibody Drug Conjugates, and Site Specific Antibody Conjugate Methods for the Treatment of Cancer

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to HUIYU Pharmaceuticals Co, Ltd located in Neijiang City, CHINA to practice the inventions embodied in U.S. Provisional Patent Application 61/833,732, filed June 11, 2013 entitled “Her2-Specific Monoclonal Antibodies and Conjugates Thereof” [HHS Ref. No.: E-351-2013/0-US-01], and International Application PCT/US2014/041492, filed June 9, 2014 entitled “Her2-Specific Monoclonal Antibodies and Conjugates Thereof” [HHS Ref. No.: E-351-2013/0-PCT-02], any PCT, US or foreign applications claiming the benefit of. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be limited to China, and the field of use may be limited to:

The use of the m860 monoclonal antibodies as mono-specific antibodies; or targeting moieties for immunoconjugates, wherein the antibodies are conjugated to auristatin F and analogues thereof, for the treatment of HER2 positive cancers.

**DATES:** Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Eggerton Campbell, Ph.D. Licensing and Patenting Manager, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5282; Facsimile: (301) 435-4013; E-mail: [Eggerton.Campbell@nih.gov](mailto:Eggerton.Campbell@nih.gov).

**SUPPLEMENTARY INFORMATION:** These inventions concern Antibody Drug Conjugates (ADCs). ADCs can demonstrate high efficacy as cancer therapeutics, however, much more can be done to improve their efficacy and safety profile. Site-specific antibody drug conjugation is a promising way to do this.

The scientists at the NIH have identified a fully human monoclonal antibody, m860, that binds to cell surface-associated Her2 with affinity comparable to that of Trastuzumab (Herceptin) but to a different epitope. In addition, the scientist developed a site-specific glycan engineering method to conjugate the antibody to the small molecule

drug auristatin F. The ADC prepared though this site-specific approach shows very good stability, cell surface binding activity and also potent specific cell killing activity against Her2 positive cancer cells, including Trastuzumab resistant breast cancer cells. This ADC has the potential to be developed as a targeted therapeutic for Her2-overexpressing cancers.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404 within thirty (30) days from the date of this published notice.

Applications for a license in the field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 30, 2014.

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Richard U. Rodriguez, M.B.A.  
Acting Director  
Office of Technology Transfer  
National Institutes of Health

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